

SEP 14 1999



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## **SECTION 2: SUMMARY AND CERTIFICATION**

### **510(K) SUMMARY**

Safety and effectiveness information concerning the Bio-logic Evoked Potential product and this Software modification is summarized below.

Because this is not a CLASS III device, the special certification defined for this section is not required.

**PREPARED BY:** Bio-logic Systems Corp  
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Mundelein, IL 60060

**TELEPHONE:** (847)-949-5200

**CONTACT PERSON:** Norman E. Brunner

**DATE ON WHICH THE SUMMARY WAS PREPARED:** August 18, 1999

**NAME OF DEVICE:** Bio-logic Evoked Potential.

**COMMON NAME:** Evoked Response System.

**CLASSIFICATION NAME:** Evoked Response Auditory Stimulator (per CFR 882-1900).

**PREDICATE DEVICE:** Bio-logic Navigator and Traveler Evoked Potential Product, reference 510(k) #K930328.

#### **DESCRIPTION OF THE DEVICE:**

The Bio-logic Evoked Potential family of products is intended to be used for the recording and analysis of human physiological data for the purpose of neurological diagnosis and treatment of sensory disorders. The predicate device referenced above is the latest in a series of systems of this type marketed by Bio-logic. Other related devices comprising the Evoked Potential family include:

1. 510(k) #K803226 – Bio-logic Evoked Response Stimulators.
2. 510(k) #K842543 – Bio-logic Evoked Potential System.
3. 510(k) #K844992 – Bio-logic Portable Evoked Response System.
4. 510(k) #K862690 – Bio-logic Traveler LT System.

The predicate device performs Evoked Potential recording and analysis functions, providing up to 8 channels of simultaneous data recording. This device has both hardware and software modifications and improvements over the related devices. Related Device #1 above is the first Evoked Potential device marketed by Bio-logic. It provides for up to 4 channels of data recording. Related Device #2 above is a hardware/software modification to the first device. Related Device #3 above is similar to #2, but utilizes a "portable" computer for ease of use and transportability. Device #4 utilizes hardware and software variations over devices #1, #2 and #3, primarily to enhance size-reduction and portability. It provides for a maximum of 2 channels of data recording. Trade names of "Traveler", "Express" and "LT" are associated with these transportable devices. Data recording hardware is available in three variations: the "E" Series, for up to 2 channels of data recording; the "SE" Series, for up to 4 channels of data recording; and the "Explorer" Series, for up to 8 channels of data recording. The Evoked Potential software is essentially the same for all of these products, with variations in models to accommodate differences in the hardware.

Evoked Potential systems can be used for three different kinds of tests: Auditory Evoked Potentials (AEP), Visual Evoked Potentials (VEP), and Somatosensory Evoked Potentials (SEP). These variations are called "modalities", and are offered as options in all three models of hardware marketed by Bio-logic. Each modality has its own unique hardware requirements. The modifications associated with this new modified device are to the software only, and do not change the hardware in any way. Also, the change only affects the operation of the Auditory Evoked Potential software functionality. There are no changes to any part of the VEP or SEP hardware or software.

The AEP test works on the basis of repeating a stimulus-response cycle. An auditory stimulation (click, tone, etc.) is presented to the patient through the use of an earphone or headphones. The EEG response from the brain is read through the use of scalp electrodes placed on the patient. The response time of interest is approximately from 1 – 20 milliseconds following the stimulus. The response voltage for this time period is amplified, digitized and stored in the AEP system computer's memory. The stimulation is then repeated, the EEG response is read again, and this cycle is repeated many times. Each time the response is read, it is averaged together with all previous responses. The final data record is the result of averaging several thousand (usually 2000-3000) responses. This averaging process is necessary because the EEG signal is very small, much lower in voltage than the surrounding EEG "noise" present in the recording. The noise is averaged out over the many readings, because the noise will have an average net value of zero. The result from the averaging process will be the signal.

Some of the EEG responses may have large amounts of noise or other artifact caused by random events such as patient movement or externally-generated electrical noise. These artifacts are usually characterized by very high amplitude voltages (relative to normal EEG levels). The EP program automatically monitors the response for abnormally-high voltage levels. When a response contains such artifacts, the response is discarded, not averaged, and not counted in the cycle count.

In preparation for running an AEP test, the user (EP Technologist, Audiologist, etc.) defines the test parameters through the use of a test protocol. In standard testing situations, most of these parameters will remain the same from test to test. One of the parameters is the number of stimulation cycles to be used. In order for the test to be completed as quickly as possible, it is desirable to use the smallest number of cycles. However, if the number of cycles is too small, the average will still contain large amounts of "noise" and the quality of the data may be lowered. In general, the higher the number of cycles, the better will be the quality and reliability of the data. So, there is a trade-off between the time to perform the test and the quality of the test results.

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Using the standard AEP program, the normal procedure would be to setup the number of stimulations for some nominal number at the lower end of the range, say 2000. The test would then be run to completion and the data manually reviewed by the user. If the quality of the data is considered to be too low, the test would be re-run with a higher number of stimulations. Another approach is for the user to set the number of stimulations to be a number on the high end of the range and continually monitor the accumulating average that is continuously displayed on the computer's monitor screen. Because the averaged data is updated to the screen every few seconds, it is possible to manually stop the test after the data looks "good enough" to the user. While this is admittedly a somewhat subjective measure not necessarily consistent from one user to the next, it is acceptable because of the training that a registered EP Technologist or Audiologist receives in the interpretation of such data records.

This Special 510(k) is for a modification to the standard Bio-logic AEP device, adding a software algorithm that automatically runs in the "background" while the AEP data recording is progressing. The purpose of this algorithm is to calculate a statistical value called "POVR", standing for "Point-Optimized Variance Ratio". For several (up to 10) strategically-selected data points at specific time latencies from the time of the stimulus, the algorithm makes a calculation intended to represent signal-to-noise ratio (S/N) at these points. This calculation is run on the accumulated data average every 256 stimulation-response cycles ("sweeps"). The result of the calculation is the POVR number, which is a statistical measure of the "power" level of the signal with respect to the noise. In normal testing, the POVR number will gradually increase as the number of sweeps increases and the resulting S/N ratio gets larger. When the POVR number reaches a specific threshold, the quality of the recording is considered to be high, and the test is automatically ended.

There are two additional conditions to the termination of the test recording:

1. The number of artifact sweeps must be lower than a pre-defined percentage of the sweeps, and
2. The number of sweeps must be greater than some pre-defined minimal number.

In addition, the maximum number of sweeps is set by the user in the AEP protocol, so that the test recording will also be ended when this maximum is reached. In this case, the POVR calculation will be below the stopping threshold, indicating that the quality of the data may still be too low. A second POVR number, less than the stopping POVR number, is used by the algorithm to make a pass/refer recommendation to the user. In any case, because the standard AEP capabilities still exist in the software, the user may evaluate the data recording and make the determination as to whether or not the recording is of acceptable quality, or if more testing is necessary.

This modification to the standard Bio-logic AEP program allows for a more objective and quantifiable measure of the data recording quality, while also achieving test completion more quickly in many cases. In those cases where the testing time is not reduced, but the POVR threshold is ultimately reached, the resulting data recording quality will likely be higher than if the same test had been performed manually. This is because the manual test is terminated when the number of sweeps reaches the pre-set number in the protocol, regardless of the quality of the result. The modified program with the POVR algorithm will continue the stimulus-response cycle until the POVR threshold is reached.

#### **INTENDED USE:**

The Bio-logic Evoked Potential (EP) product family is intended for use in the recording and analysis of human physiological data necessary for the diagnosis of auditory and hearing-related disorders. An auditory stimulus (click, tone, etc.) is presented to the patient's ear through an earphone or headphones, and the

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Brainstem Auditory Evoked Response from the patient is recorded using EEG electrodes placed on the scalp. Although this Brainstem Response is very low in amplitude (with respect to surrounding EEG “noise”), the stimulus-response cycle is repeated many times and the resulting responses are averaged from the time of the stimuli. The random noise averages to zero, but if the Brainstem Response signal is present, it’s signal will be easily determined in the averaged signal.

The Bio-logic AEP System can be used for patients of all ages, from children to adults, including infants and geriatric patients. It is especially indicated for use in testing individuals for whom behavioral audiometric results are deemed unreliable, such as infants, young children, and cognitively impaired or uncooperative adults. The use of the Bio-logic EP family of products is to be performed under the prescription and supervision of a physician or other trained health care professional.

The primary feature modification represented in this Special 510(k) is for the use of a new algorithm and protocol to generally assist in test data interpretation, and specifically assist in the assessment of signal-to-noise ratio and the quality of the Brainstem Auditory Evoked Response in infants. Based on this automatic assessment, the speed of testing may be reduced and/or the quality of the data recording may be improved. This new feature is used in conjunction with the current EP program, without compromising the quality of recorded data or limiting the control and flexibility of the health care professional administering the test.

## **SAFETY AND EFFECTIVENESS SUMMARY**

To establish the safety and effectiveness of this modification to the Bio-logic Evoked Potential software, the modification was designed and incorporated into the product in accordance with the Bio-logic internal Product Development procedures which are intended to meet ISO-9001 and FDA QSR Design Control specifications. A detailed Hazard/Risk analysis was performed using the Fault Tree analysis (FTA) approach, and a detailed Risk Assessment was written in accordance with EN-1441, the International Standard for Hazard/Risk analysis.

Because this modification to Evoked Potential consists of only software, there are no newly-introduced hardware-related methods by which the patient can be harmed or injured through the use of this device. In addition, the program does not make any final decisions that result in any automatic forms of diagnosis or treatment. All program “recommendations” are subject to review by the EP Technologist or Physician, and may be modified, overridden or deleted as determined by a qualified user. The program provides extensive functionality to allow the qualified user to review all raw data collected and otherwise customize the data analysis to suit his or her requirements.

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The following comparison is provided as a summary of technological characteristics relative to the predicate Evoked Potential devices. This is to demonstrate that this new modification to the Evoked Potential program has no significant differences which would adversely affect product safety and effectiveness.

Parameter for comparison	Similarity or Difference
Intended Use	No differences.
Population	No differences. However, the optimal POVR points may differ between infant and adult populations. The present POVR algorithm is optimized for infants.
Hardware Configuration	This modified program is primarily intended to be used with the Bio-logic 2-channel "E" Series hardware, but can also be used with the 4-channel "SE" Series hardware.
Computer Control Software	The fundamental EP software is unchanged, except for the addition of the POVR algorithm running in the background.
Patient information and tracking.	No differences.
Performance	The use of the POVR algorithm will usually reduce time for test completion, and offers an objective basis for determination of data recording quality.
Safety Characteristics	No differences. There is no change to any of the patient-connected hardware or the hardware control software. There is no change to the basic computer hardware required or to the computer operating system.
Product Labeling	No differences.
Anatomical sites.	No differences.
Physical Characteristics	No differences.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 14 1999

Mr. Norman E. Brunner  
Vice-President of Research and Development  
Bio-logic Systems Corp.  
One Bio-logic Plaza  
Mundelein, Illinois 60060-3700

Re: K992807  
Trade Name: Biol-logic Evoked Potential for ABAER I  
Product Code: GWQ  
Dated: August 19, 1999  
Received: August 20, 1999

Dear Mr. Brunner:

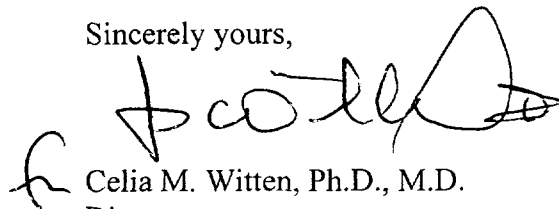
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'C. Witten', with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known):

Not Assigned

K992807

Device Name: Modification to Bio-logic Evoked Potential for ABAER I

## Indications For Use:

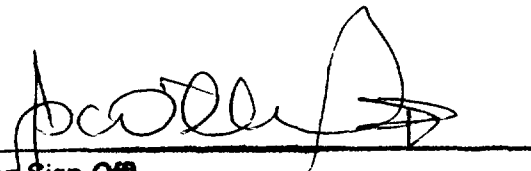
The Bio-logic Evoked Potential (EP) product family is indicated for use in the recording and analysis of human physiological data necessary for the diagnosis of auditory and hearing-related disorders. An auditory stimulus (click, tone, etc.) is presented to the patient's ear through an earphone or headphones, and the Brainstem Auditory Evoked Response from the patient is recorded using EEG electrodes placed on the scalp. Although this Brainstem Response is very low in amplitude (with respect to surrounding EEG "noise"), the stimulus-response cycle is repeated many times and the resulting responses are averaged from the time of the stimuli. The random noise averages to zero, but if the Brainstem Response signal is present, it's signal will be easily determined in the averaged signal.

The Bio-logic EP System can be used for patients of all ages, from children to adults, including infants and geriatric patients. It is especially indicated for use in testing individuals for whom behavioral audiometric results are deemed unreliable, such as infants, young children, and cognitively impaired or uncooperative adults. The use of the Bio-logic EP family of products is to be performed under the prescription and supervision of a physician or other trained health care professional.

The primary feature modification represented in this Special 510(k) is for the use of a new algorithm and protocol to generally assist in test data interpretation, and specifically assist in the assessment of signal-to-noise ratio and the quality of the Brainstem Auditory Evoked Response in infants. Based on this automatic assessment, the speed of testing may be reduced and/or the quality of the data recording may be improved. This new feature is used in conjunction with the current EP program, without compromising the quality of recorded data or limiting the control and flexibility of the health care professional administering the test.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K992807

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)